

Attorney Docket No.: 266/165 (UMD-0032)  
Inventors: Madura, Kiran  
Serial No.: 09/918,036  
Filing Date: July 30, 2001  
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#### **REMARKS**

Claims 6, 7, 9, 10, and 12 are pending in the instant application. Claims 6, 7, 9, 10, and 12 have been rejected. Claims 6 and 10 have been amended. No new matter has been added by this amendment. Reconsideration is respectfully requested in light of the following remarks.

#### **I. Rejections Under 35 U.S.C. §112**

Claims 6, 7, 9, 10, and 12 have been rejected under U.S.C. §112, first paragraph, for lacking a sufficient written description of the term "catalytically active 26S proteasome." The Examiner suggests that there is nothing to suggest in the specification, or the claims as originally filed, that Applicant limited their method to the cells with a catalytically active 26S proteasome. It is suggested that this term constitutes new matter which was not described in the specification in such a way as to reasonably convey to one skilled in the art that the inventor had possession of the claimed invention. It is suggested that the structure of the 26S proteasome is complex and there is no teaching which mutants of which components of the proteasome influence catalytic activity. Applicant respectfully disagrees with this rejection.

MPEP 2163.06 states that "information contained in any one of the specification, claims or drawings of the application as filed may be added to any other part of the application without introducing new matter." As acknowledged by the Examiner, the specification at page 42, lines 4-12, states that "a common biochemical property of a UbL is its interaction with

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catalytically active 26S proteasome." Accordingly, the rejection of the phrase "catalytically active 26S protease" as new matter is improper.

Further, Applicant respectfully disagrees with the Examiner's suggestion that there is nothing to suggest in the specification, or the claims as originally filed, that Applicant limits the instant method to cells with a catalytically active 26S proteasome. As is well-known in the art, defects in the ATP-dependent proteasome pathway generally result in lethality and only conditional mutants can be analyzed, as exemplified in the instant specification. Accordingly, as originally filed, the claims were drawn to assessing the proliferative potential of malignant cells, which generally exhibit a gain-of-function in this pathway. See Applicant's response dated February 25, 2005. Thus, at the outset, Applicant has claimed a cell with a catalytically active 26S proteasome because malignant cells are considered viable cells with gain-of-function mutations in the 26S proteasomal pathway.

In re Marosi, 710 F.2d 799,218 USPQ 289 (Fed. Cir. 1983) "Claims are not to be read in a vacuum, and limitations therein are to be interpreted in light of the specification in giving them their broadest reasonable interpretation." 710 F.2d at 802, 218 USPQ at 292 (quoting In re Okuzawa, 537 F.2d 545, 548, 190 USPQ 464, 466 (CCPA 1976)).

In the analysis of various yeast mutants with defects in proteasomal activity (i.e., *ufdΔ*, *cim5-1* and *pre1-1 pre2-2*), Applicant established a correlation between the need for a catalytically active 26S proteasome to degrade an UbL containing protein. MPEP 2111.01 indicates the words of a claim must be read

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as they would be interpreted by those of ordinary skill in the art. In re Sneed, 710 F.2d 1544, 218 USPQ 385 (Fed. Cir. 1983). Based on these teachings of the specification, the skilled artisan would readily give the term "catalytically active 26S proteasome" its plain meaning, i.e., a proteasome exhibiting measurable activity, e.g., to degrade UbL containing proteins. In this regard, the written description requirement has been met because the specification has clearly conveyed to one of skill in the art that Applicant was in possession of that which is claimed. Thus, Applicant respectfully requests reconsideration and withdrawal of this rejection.

Claims 6, 7, 9, 10, and 12 have been rejected under 35 U.S.C. §112, first paragraph, because the specification, while being enabling for degradation of Rad23<sup>1-369</sup>, Rad23-HA and Ubl<sup>R23</sup>-lacZ with 0-30 min. after labeling when the labeling is performed in some exponentially growth yeast transformants (Figures 7 and 9), does not reasonably provide enablement for assessing whether a cell with a catalytically active 26S proteasome is quiescent or actively growing. It is acknowledged that the art of construction of DNA molecules encoding fusion proteins is highly developed and skill of the artisan is high; however, it is suggested that because Applicant has not defined a catalytically active 26S proteasome or a cell with a catalytically active 26S proteasome, one skilled in the art would not know which cell to choose for transfection and assessment. It is further suggested that a determination of whether a cell has the catalytically active 26S proteasome is left to be determined by the skilled artisan. Applicant respectfully disagrees.

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Applicant has disclosed illustrative examples of yeast cells with a catalytically active 26S proteasome (e.g., the wild-type cells of the paragraph bridging pages 34 and 35) as well as cells lacking a catalytically active 26S proteasome (e.g., *cim5-1* and *pre1-1 pre2-2* cells of the paragraph bridging pages 36 and 37). Thus, Applicant has provided the necessary guidance to one of skill as to which yeast cell to choose for transfection and assessment. In an earnest effort to facilitate the prosecution of the present application, Applicant has amended the claims to clarify that the cell being assayed is a yeast cell with a catalytically active 26S proteasome. Support for this amendment is found in the specification at pages 34-37 which illustrate the assessment of growth of yeast cells with a catalytically active 26S proteasome. As such, Applicant has provided at least one method for making and using the claimed invention which bears a reasonable correlation to the entire scope of the claim and therefore the enablement requirement has been satisfied. In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). MPEP 2164.01(b). It is therefore respectfully requested that this rejection be reconsidered and withdrawn.

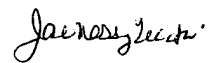
## **II. Conclusion**

The Applicants believe that the foregoing comprises a full and complete response to the Office Action of record.

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Accordingly, favorable reconsideration and subsequent allowance of the pending claims is earnestly solicited.

Respectfully submitted,



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